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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------|---------------------|------------------|
| 10/781,333 | 02/17/2004 | Keith Leslie Williams | Q107293 | 9422 |
| 23373 7590 07/11/2008 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037 | | | | |
| EXAMINER GORDON, BRIAN R | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1797 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/781,333

Applicant(s)

WILLIAMS ET AL.

Examiner

Brian R. Gordon

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4-30-08.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 11-19, 21, 25-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/403,196.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Response to Arguments

Applicant's arguments filed April 3, 2008 have been fully considered but they are not persuasive. As to the art rejection, applicant's arguments are directed to intended use. Specifically applicant asserts "Although Balch discloses a proximal CCD-based imager, the proximal CCD-based imager is only used for acquisition and displaying of the hybridization test results and is not used for determining positions of the samples." Each of the claimed elements (a)-(d) include "that" phrases that describe how the elements are intended to be used with an unclaimed sample. While the preamble states the device is for analysing at least one sample in an array of samples, the array of samples are not positively claimed as an element of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. The CCD imaging system of Balch et al is capable of "recording" the position of biosites in the arrays. (see column 6, lines 31-41). Furthermore Balch et al. discloses the system may comprise a scanning mechanism (column 30, lines 43-51).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4, 11-19, 21, and 25-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Balch et al. US 6,479,301

Balch et al. devices for preparing a reaction substrate for use as an assay device, and methods of using these devices. The devices prepare reaction substrates comprising arrays of biosites bound to reaction substrates. The devices have a plurality of bundled capillary tubes that convey capture probes from a storage area for eventual deposition onto a biosite on a reaction substrate.

Each biosite comprises a circle of approximately 25-200 microns in diameter. (column 9, lines 46-47).

The multiplexed assay can be designed in a standard 96 well microtiter plate format for room temperature operation to accommodate conventional robotic systems utilized for sample delivery and preparation. Also, the proximal CCD-based imager (image recorder) with a graphical user interface will enable the automation of the parallel acquisition of the numerous hybridization test results. The CCD imaging system software provides automated filtering, thresholding, labeling, statistical analysis and quantitative graphical display of each probe/target binding area within seconds (column 6, line 31+).

The accompanying proximal CCD detector/imager offers high spatial and digital resolution. In the preferred embodiment, CCD will support the imaging of hundreds to

thousands of individual biosites on a reaction substrate. Together with 16 bit digital imaging, a highly quantitative image of the high density of biosites is achieved.

Specifically the device includes an ink-jet printer to be employed for printing the biological fluids to form the biosites, a proximal CCD detector/imager, bound universal capture probes are arranged in an array of biosites attached to a solid support (for extraction), various labels for identifying molecules, the CCD can provide simultaneous imaging and spectroscopy (analyzer) in the same image.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, 1st Fri. Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian R Gordon/
Primary Examiner
Art Unit 1797

Brian R. Gordon

1797

| INTERFERENCE SEARCHED | | | |
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| Class | Subclass | Date | Examiner |
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